



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,731	09/27/2005	Vesna Skulj	RG/G-32919A	3189
72554	7590	05/07/2008		
SANDOZ INC 506 CARNEGIE CENTER PRINCETON, NJ 08540			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 05/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,731

Applicant(s)

SKULJ ET AL.

Examiner

FRANK I. CHOI

Art Unit

1616

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-12 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-12 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-12, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zmitek et al. (US Pat. 5,498,788) in view of Buckton et al., Sherwood et al. (US Pat. 5,585,115) and Czap.

Zmitek et al. disclose a rapidly disintegrating tablet containing potassium clavulanate, amoxicillin trihydrate, magnesium stearate and microcrystalline cellulose (MCC) which is prepared by homogeneously mixing the ingredients, sieving and tableting (Column 11, lines 5-31).

Buckton et al. disclose that silicified microcrystalline cellulose (SMCC) has advantages over conventional MCC in tableting in that it has superior flow properties (Abstract).

Sherwood et al. disclose that SMCC possesses excellent disintegration properties and is free-flowing, has improved compressibility versus standard commercially available MCC and has higher tablet strength versus MCC (Column 4, lines 34-68, Column 5, lines 1-10, Column 11, lines 34-45, Column 15, lines 36-68, Column 16).

Czap disclose that hydrogenated castor oil is used as a lubricating aid in tablets similar to stearic acid or stearic acid complexed with magnesium (See Editorial).

The prior art discloses a rapidly disintegrating tablet containing potassium clavulanate, amoxicillin trihydrate, magnesium stearate and microcrystalline cellulose which is prepared by homogeneously mixing the ingredients, sieving and tableting. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of SMCC or hydrogenated castor oil. However, the prior art amply suggests the same as the prior art discloses that silicified microcrystalline cellulose and hydrogenated castor oil are excipients used in tableting. As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation that substitution of silicified microcrystalline cellulose would facilitate the tableting process and that hydrogenated castor oil would be a suitable substitute for magnesium stearate as a lubricating aid in the tableting process.

The Examiner had duly considered the Applicant's arguments but deems them unpersuasive.

Contrary to the Applicant's arguments, the claims do not exclude superdisintegrants. The limitation "substantially free" is not defined by the Specification or claims. As such, the Applicant has not shown that the amount of crospovidone in the Zmitek example is a substantial amount.

The Applicant argues that the Buckton reference would not have lead a person of ordinary skill in the art to substitute SMCC in place of MCC because Buckton discloses that the SMCC has a higher tablet strength and higher compressibility after wet granulation. However, the Applicant has not provided any evidence that this difference would result in tablets incapable of rapidly disintegrating or that one of ordinary skill in the art would have considered higher tablet strength and higher compressibility after wet granulation to be drawbacks to rapidly

Art Unit: 1616

disintegrating tablets. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) (“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness.”). In any case, as indicated in *Sherwood et al.* above, SMCC has excellent disintegration properties. As such, the Applicant has not shown that the higher tablet strength and compressibility after wet granulation of SMCC versus MCC are drawbacks to rapid tablet disintegration.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi

Patent Examiner

Technology Center 1600

May 7, 2008

Application/Control Number: 10/518,731
Art Unit: 1616

Page 5

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616